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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/170,344	03/30/1994	WYBE M. KAST	D45113TFM	4000

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EXAMINER	
MINNIFIELD, NITA M	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/170,344	KAST ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-16 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4-16 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 70 pgs.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 01-04-94 2 pgs.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment filed May 28, 2004 is acknowledged and has been entered. Claims 1, 3 and 17-24 have been canceled. Claims 5, 6, 8, 10, 12, 14 and 16 have been amended. Claims 2, 4-16 and 25 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments with the exception of those discussed below. This is a NON-FINAL Office Action.

2. Applicants filed a terminal disclaimer on August 18, 2004. However, this terminal disclaimer has not been accepted because there is no application serial number or issued patent number that would indicate what is being disclaimed. Further, there is no ODP or provisional ODP rejection of record. A terminal disclaimer is not required with regard to the pending rejections.

3. Claims 25, 2, and 4-16 are objected to because of the following informalities: see line 3 of claim 25 which recites "...E6 or E7 of HPV or HPV18..." should this be "...E6 or E7 of HPV16 or HPV18..." Also see claim 25 line 5; do Applicants "major histocompactability complex" or "major histocompatibility complex"? Appropriate correction is required.

4. The objection to the specification and rejection of claims 25, 5, 6, 8, 10, 12, 14 and 16 under 35 U.S.C. 112, first paragraph (i.e. lack of an enabling disclosure) is maintained. The objection and rejection are maintained for essentially the same

reasons as set forth in the last office action. Applicants' arguments filed May 28, 2004 have been fully considered but they are not deemed to be persuasive.

Claim 25 is directed to a peptide comprising an amino acid sequence derived from protein of human papilloma virus (HPV), wherein said amino acid sequence comprises a nonapeptide derived from protein E6 or E7 of HPV16 or HPV18 and wherein said nonapeptide has the ability to bind in the grooves on top of the human major histocompatibility complex (MHC) Class I molecule.

Claims 5, 6, 8, 10, 12 and 14 are directed to peptides according to claim 25, comprising an amino acid sequence derived from protein E6 or E7 of HPV16 or HPV18, wherein said amino acid sequence has the ability to bind to various human MHC Class I alleles and is selected from a group consisting of peptides defined by SEQ ID NO: and a variant of any one of these amino acid sequences differing by one conservative amino acid substitution which has the ability to bind to various human MHC Class I alleles.

Claim 16 is directed to a pharmaceutical composition containing an effective amount for eliciting cellular immune response of a peptide according to claim 25 and a pharmaceutically acceptable carrier, diluent, excipient or adjuvant.

With regard to claim 16, a pharmaceutical composition, the specification does not teach how to use a the pharmaceutical composition containing an effective amount for eliciting cellular immune response of the peptide derived from E6 or E7 of HPV16 or HPV18 and a pharmaceutically acceptable carrier, diluent, excipient or adjuvant. The disclosure is enabled for nonapeptide sequences from the E6 or E7 genes of HPV16 or HPVI8, and MHC Class I molecules as specifically taught in the specification. The specification contemplates that the pharmaceutical compositions can be used for prevention, prophylaxis, therapy and

treatment of cervical carcinoma and/or adenoma and other HPV-related, in particular HPV16- and/or HPV18-related diseases (see p. 3, l. 31-35). The specification states that the "novel peptides of the present invention are useful in pharmaceutical compositions, as screening tools and in the prevention, prophylaxis, therapy and treatment of HPV16- and/or HPV18-induced diseases or other conditions which would benefit from inhibition of HPV16 and/or HPV18 infection." (see p. 4, l. 12-16) However, the specification does not teach how to use the claimed pharmaceutical composition in the treatment of HPV16- and/or HPV18-induced diseases comprising administering the pharmaceutical composition to a subject. The only evidence provided in the specification is in vitro data showing induction of primary immune response against HPV peptides. The data shows that the peptides bind to MHC Class I alleles. It is noted that a when a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that use. In this case, the specification must teach enablement of a pharmaceutical use since the claim recites a pharmaceutical composition. A pharmaceutical use would be any use, other than as food, wherein a substance is used on or in the body to prevent, diagnose, alleviate, treat, or cure a disease in humans or animals. The following are examples of "pharmaceutical uses": administering vitamin supplements (preventing disease); using labeled antibodies for *in vivo* imaging (diagnosing disease); administering a substance to alleviate a symptom of a disease (alleviating or treating disease); and administering an antibiotic (curing bacterial infection). Thus, to enable a pharmaceutical use for a substance, the specification must teach how to use the substance, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure a disease in the animal or subject to which the substance is administered. The instant

specification is not enabled for such a pharmaceutical composition. Applicants have asserted that the peptides that bind to MHC-I are by definition capable of eliciting a cellular response when present. This is inherent in the workings of the immune system and well known to one skilled in the pertinent art. An immune response is automatically triggered upon presentation of a peptide by MHC-I. However, inducing an immune response is not a pharmaceutical use since it does not appear that any disease (i.e. HPV16- or HPV18-related diseases) has been alleviated, treated or prevented. Administering the claimed peptides to a subject to produce antibodies which are then collected and used in an assay to diagnose the presence of HPV16- or HPV18-related diseases does not provide enablement for the claim because using the compound merely to produce antibodies for collection and subsequent use is not a pharmaceutical use. The pharmaceutical use must occur within the animal or subject to which the compound is administered for the prevention, diagnosis, alleviation, treatment, or cure of disease. Further, such short peptides require immunogenic carriers to ensure an immune response. The claimed composition does not set forth the use of any carriers.

The specification has not provided sufficient evidence that the claimed pharmaceutical composition can be used for its intended purpose. Matlashewski et al. discloses that HPV18 proteins (E6 gene) maybe diagnostically useful since the proteins have been identified in specific human cancers, however the use of the pharmaceutical composition as claimed in this invention are not known in the art. Accordingly, amendment of the claims to what is supported in the specification or filing of evidence in the form of a Rule 1.132 declaration providing factual evidence supporting the broad range claims is suggested.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, In re Glass, 18 1 USPQ 31; 492 F2.d 1228 (CCPA1974). While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

Specific operative embodiments or examples of the invention must be set forth Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a compound is stated only as probability and speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound. Incomplete teachings may not be completed by reference to subsequently filed applications.

The instant specification invites the skilled artisan to experiment. The factors, which must be considered in determining undue experimentation are set forth in Ex parte Forman 230 USPQ 546. The factors include 1) quantity of experimentation necessary, 2) the amount of guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the predictability of the art and the 7) breath of the claims. With regard to factors three and six, it is noted that there are no working examples or support for in vivo efficacy of the active ingredients in a pharmaceutical composition for therapeutic treatment of a human with cervical carcinoma or other HPV related diseases by administering a peptide from HPV proteins in a pharmaceutical

composition, or peptides from any HPV that bind to MHC Class I molecules. Such is not seen as sufficient to support the breath of the claims, wherein the scope of the claims encompasses how to prepare a peptide from any of the listed HPV proteins (or any other HPV protein) wherein the peptide binds to any human MHC Class I molecule. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves., see In re Gardner et al. 166 USPQ 138 (CCPA 1970).

Applicants have argued that the specification is enabled and have cited Ruppert et al., Kast et al., Feltkamp et al., Vitiello et al., and Ressing et al. as support to demonstrate enablement, however it is noted that the specification must be enabled as of its filing date. Prior art references that were published after Applicants' effective filing date (5-5-92) cannot be used to rebut prima facie case of nonenablement under 35 USC 112. In re Glass, 181 USPQ 31; 492 F2.d 1228 (CCPA 1974).

Applicants have argued that it would be unethical to demonstrate HPV treatment in humans, however the Examiner has not suggested such a demonstration. Applicants have not demonstrated treatment of HPV in animal models. With regard to the therapeutic treatment, it appears that the specification is a paper protocol. The specification does not show any therapy or prophylactic treatment, only in vitro studies; no animal studies using the peptides to demonstrate prophylactic or therapy treatment that would correlate to human efficacy have been set forth in the specification. Applicants have argued that Kast et al. (PNAS, 1991, 88:2283-2287 and Immunol. Letters, 1991, 30(2):229-232) show that one of skill in the art would readily understand from these references how to make and use the

claimed invention. Kast et al. (1991, PNAS) disclose the immunization of synthetic peptides of Sendai virus, not HPV. Further, Kast et al. (1991, Immunol. Letters) does disclose the use of peptide vaccination, however the use of HPV peptides is not discussed. HPV is discussed with regard to using "... cultured human CTL for immunotherapy of virus-induced tumors" (p. 229). Furthermore, the reference discloses that there are several unanswered questions regarding peptide vaccination as a novel immunotherapeutic or preventive approach in man (summary; p. 230, col. 2).

Claims 5, 6, 8, 10, 12 and 14 are directed to peptides according to claim 25, comprising an amino acid sequence derived from protein E6 or E7 of HPV16 or HPV18, wherein said amino acid sequence has the ability to bind to various human MHC Class I alleles and is selected from a group consisting of peptides defined by SEQ ID NO: and a variant of any one of these amino acid sequences differing by one conservative amino acid substitution which has the ability to bind to various human MHC Class I alleles. The specification discloses that variants include any amino acid substitution (p. 17). Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity/utility requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a single protein and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect

thereto is extremely complex (Bowie et al. 1990; p. 1306, p. 1308) and is well outside the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity/utility are limited in protein and the result of such modifications is unpredictable based on the instant disclosure.

The specification does not support the broad scope of the claims which encompass all variants of the protein because the specification does not disclose the following: the general tolerance to modification (substitution, insertion, deletion) and extent of such tolerance; specific positions and regions of the sequence(s) which can be predictably modified and which regions are critical; what variants, if any, can be made which retain the biological activity of the intact protein; and the specification provide essentially no guidance as to which of the essentially infinite possible choices is likely to be successful. Further, Houghten et al. teach that changes/modifications (addition, substitution, deletion or inversion) of one or more amino acids in a polypeptide will alter antigenic determinants and therefore effect antibody production (p. 21) as well as antibody binding. Houghten et al. also teach that "...combined effects of multiple changes in an antigenic determinant could result in a loss of (immunological) protection." and "A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies..." (p. 24). Houghten et al. teach that point mutations at one key antigen residue could eliminate the ability of

an antibody to recognize this altered antigen (p. 24). It is not always possible to make the derivatives that retain immunodominant regions and immunological activity if the regions have been altered.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed protein in a manner reasonably correlated with the scope of the claims broadly including any member of insertions, deletions or substitutions encompassing a variant, fragment, derivatives, homologs, isoforms etc as presently claimed. The scope of the claims must bear a reasonable correlation will the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made in the protein structure and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. The sequence of some proteins is highly conserved and one skilled in the art would not expect tolerance to any amino acids modification in such proteins. However, even if it were shown that some modifications could be tolerated in the claimed peptides, for the reasons discussed the claims would still expectedly encompass a significant member of inoperative species, which could not be distinguished without undue experimentation. See Amgen. Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and Ex parte Forman, 230 U.S.P.Q. 546 (Bd. Pat. App. & Int. 1986).

Applicants have asserted in the May 28, 2004 response that the claims have been amended to obviate the rejection. However, as previously stated the claims still recite "variant" language.

5. The rejection of claims 2, 4, 7, 9, 11, 13, 15, 16 and 25 under 35 U.S.C. 102(b) as anticipated by Schoolnik et al. (EP0257754) is maintained. This rejection is maintained for essentially the same reasons as set forth in the last office action.

Schoolnik et al. discloses synthetic peptides from HPV that are useful in the diagnosis and therapy of conditions associated with HPV infection (abstract; p. 9, l. 10-18; claims). Schoolnik et al. teaches the preparation of peptides from HPV16 (E6 and E7) or other HPV proteins useful to raise antibodies for diagnostic, protective (i.e. prophylactic), and therapeutic purposes and vaccines, as well as various mode of administration (p. 3, l. 1-39; p. 5, l. 28-50; p. 4, l. 27 to p. 5, l. 24; p. 7, l. 47 to p. 8, l. 8).

It is noted that the claims recite a peptide comprising an amino acid sequence from a protein of E6 or E7 of HPV16 or HPV 18. The prior art of Schoolnik et al. anticipates the claimed invention by disclosing a peptide from a HPV protein wherein the peptide binds to a MHC Class I molecule, and a method of prophylactic or therapeutic treatment of a human with cervical carcinoma or other HPV related diseases by administering a peptide from HPV proteins in a pharmaceutical composition. The peptides and compositions disclosed in Schoolnik et al. are believed to inherently possess properties, which anticipates the claimed invention since the prior art peptides are from the same source, E6 or E7 of HPv16 or HPV18. The property of the ability to bind in the grooves on top of MHC Class I molecules is inherent, since Schoolnik et al discloses the same peptides.

Since the Office does not have the facilities for examining and comparing applicants' HPV peptides and compositions and the HPV peptides and compositions of the prior art, the burden is on applicant to show a novel or

unobvious differences between the claimed HPV peptides and compositions and the HPV peptides and compositions of the prior art (i.e., that the peptide and composition of the prior art does not possess the same material structural and functional characteristics of the claimed peptides and compositions). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald, 205 USPQ 594.

Applicants' arguments filed May 28, 2004 have been fully considered but they are not deemed to be persuasive. Applicants' comments have been addressed previously. Applicants disagree with the Examiner's interpretation of the teachings of Schoolnik. "Schoolnik teaches HPV16 E6 and E7 peptides and HPV proteins, which may be used to raise antibodies for diagnostic and therapeutic purposes. The subject invention, on the other hand, provides peptides comprising an amino acid sequence derived from protein of human papilloma virus (HPV), wherein the amino acid sequence comprises a nonapeptide derived from protein E6 or E7 of HPV or HPV 18, and wherein the nonapeptide has the ability to bind in the grooves on top of the human major histocompatibility complex (MHC) Class I molecule, as well as pharmaceutical compositions comprising this nonapeptide. These features are recited in the claims. As stated above, the basis for this invention is applicants' discovery of HLA class I binding peptides of HPV16 and HPV18 with CTL inducing properties. Schoolnik does not disclose peptides comprising the claimed sequences combined with the claimed features of the peptides. In addition, Schoolnik does not disclose peptides which bind to the MHC Class I molecule or that are cytotoxic to T lymphocyte epitopes. Schoolnik discloses peptides which would induce a B-cell response, not a CTL response. In

fact, Schoolnik does not disclose any of the peptides claimed in the instant invention." (Remarks p. 14)

However, the rejected claims do not recite any specific amino acid sequence. The peptides disclosed in Schoolnik et al were derived from the same source as Applicants' peptides, E6 or E7 of HPV16 or HPV18. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

With regard to claim 16, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey , 152 USPQ 235 (CCPA 1967); In re Otto , 136 USPQ 458, 459 (CCPA 1963). See MPEP 2111.02

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Applicants have asserted that the subject invention provides for inducing an immune response through T-cell mediated immunity. No antibodies are

contemplated in this invention, only peptides presented to MHC-I to elicit an immune response have been envisaged. Schoolnik merely discusses the raising of antibodies to viral proteins, but does not illicit an immune response. The antibodies raised would presumably be used as a therapy to HPV related diseases. The T-cell mediated response and the antibody response are separate and distinct types of immunity. Schoolnik does not address, contemplate or suggest the T-cell mediated immunity through the presentation of the claimed peptides by MHC-I to illicit an immune response as is claimed in the subject invention.

It is inherent that the peptides of Schoolnik et al will induce the same immune response as claimed by Applicants since the source of the peptides is the same. Further, it is noted that artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient, which is inherently contained in the prior art. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)

6. Claims 25, 4, 7, 9, 11, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tindle et al (PNAS, July 1991, 88:5887-5891) or Comerford et al (J. Virology, Sept. 1991, 65/9:4681-4690).

Tindle et al discloses peptides from E7 of HPV16 (abstract). Peptides from E7 of HPV16 are disclosed in Table 1 on p. 5888, Table 2 on p. 5890 and Figure 1. Tindle et al discloses a pharmaceutical composition comprising the peptide and an adjuvant (materials and methods, p. 5888, col. 1).

Comerford et al discloses T- and B-Cell epitopes of E7 of HPV 16 (title; abstract). Comerford et al discloses synthetic peptides from E7 of HPV16 in Figure 1, p. 4683. Comerford et al discloses a pharmaceutical composition comprising the peptide and pharmaceutically acceptable carrier (PBS) or an adjuvant (materials and methods, p. 4682, col. 1).

It is noted that the claims recite a peptide comprising an amino acid sequence from a protein of E6 or E7 of HPV16 or HPV 18. The prior art anticipates the claimed invention by disclosing a peptide from a HPV protein wherein the peptide binds to a MHC Class I molecule, and a pharmaceutical composition. The peptides and compositions disclosed in Tindle et al or Comerford et al are believed to inherently possess properties, which anticipates the claimed invention since the prior art peptides are from the same source, E6 or E7 of HPV16 or HPV18. The property of the ability to bind in the grooves on top of MHC Class I molecules is inherent, since Tindle et al or Comerford et al discloses the same peptides.

Since the Office does not have the facilities for examining and comparing Applicants' HPV peptides and compositions and the HPV peptides and compositions of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed HPV peptides and compositions and the HPV peptides and compositions of the prior art (i.e., that the peptide and composition of the prior art does not possess the same material structural and functional characteristics of the claimed peptides and compositions). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald, 205 USPQ 594.

7. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

August 16, 2005